



Kent Innovation Centre
Millennium Way
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CT10 2QQ

ISRCTN Results System Prototype ([link](#))

Summary of the PHUSE Data Transparency Working Group's Feedback Submitted Online Via Prototype Link

Form fields highlighted in purple

Role, organisation or other information:

Dear ISRCTN Team

We would like to thank you for the opportunity to review and provide feedback on the new results system prototype. The feedback was developed by a diverse group of experts from the PHUSE Data Transparency Working Group.

For the purposes of providing feedback, we have tested the fields, and we are not submitting any results. We noticed the option to submit the form is greyed out since the ISRCTN results system prototype disables the submit button while in Review Mode. I am pleased to share a summary of comments, included in the ISRCTN results system prototype feedback collated from our review at PHUSE.

We are an independent, not-for-profit organisation run by a worldwide team of volunteers providing the healthcare industry with a premier platform for open-access knowledge sharing of ideas, tools and standards around data, statistical and reporting technologies. PHUSE has become the industry voice to regulatory agencies and standards organisations such as the FDA, the EMA and CDISC.

Our team have very much enjoyed being part of this important initiative to give feedback and drive forward the future of clinical trials.

Please feel free to reach out if you have any queries.

Many thanks

Devaki Thavarajah
PHUSE Data Transparency Working Group Lead
devaki.thavarajah@phuse.global

Respectfully submitted on behalf of the PHUSE Data Transparency Working Group

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Please tell us about your experience with registries:

- ☐ I register most studies on ISRCTN
- ☒ I register most studies on ClinicalTrials.gov/another registry
- ☐ I do not register studies

**Please provide any additional information such as your
role and organisation**

Enter your role, organisation or other information...

[→ Click here to review the form](#)

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 ISRCTN
The UK's Clinical Study Registry

Results Submission

This form allows you to submit summary results from your study and meet World Health Organisation (WHO) requirements and UK regulations

To view a PDF of the form [click here](#) (to be added)

Please select one of the options below:

I want to:

- ☒ Review the form without submitting results
- ☐ Submit results for a study registered on ISRCTN
- ☐ Submit results for a UK study registered on ClinicalTrials.gov
- ☐ Submit results for a UK study registered on a different registry
- ☐ Continue submitting saved (but not submitted) results
- ☐ Update submitted results

Review Mode

You will be able to view all sections of the form.

Any data entered will not be saved and submission of data to the registry will be disabled.

← Back

→ Continue



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Example screenshots:

Results Sections Contents Page – Before Completion

REVIEW MODE

You are viewing the form in review mode. Any data entered will not be saved and submitting data to the registry is disabled.

For testing the prototype you can mark all sections complete. Otherwise Participant Flow needs to be completed before some other sections can be accessed

Mark All Complete

Results Submission Form

Please select a section to edit

Conflicts of Interest

Protocol & Statistical Analysis Plan

Completion Status

Publication Status

Plain Language Summary

Data Sharing Plan

Participant Flow

Baseline Characteristics

Outcome Measures

Adverse Events

Study Conclusion

Share Reusable Data

All sections must be completed before submission.
You can exit the form and return to complete sections you have saved but not completed.

← Back

Exit Form

Results Sections Contents Page – After Completion

REVIEW MODE

You are viewing the form in review mode. Any data entered will not be saved and submitting data to the registry is disabled.

For testing the prototype you can mark all sections complete. Otherwise Participant Flow needs to be completed before some other sections can be accessed

Mark All Complete

Results Submission Form

Please select a section to edit

☑ Conflicts of Interest (Completed)

☑ Protocol & Statistical Analysis Plan (Completed)

☑ Completion Status (Completed)

☑ Publication Status (Completed)

☑ Plain Language Summary (Completed)

☑ Data Sharing Plan (Completed)

☑ Participant Flow (Completed)

☑ Baseline Characteristics (Completed)

☑ Outcome Measures (Completed)

☑ Adverse Events (Completed)

☑ Study Conclusion (Completed)

☑ Share Reusable Data (Completed)

All sections are complete
Please review the confirmations below before submitting your results to the registry.

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Page disclaimer located at the bottom of the Contents page:

(Checkboxes are greyed out since the ISRCTN results system prototype disables the submit button in Review Mode.)

All sections are complete
Please review the confirmations below before submitting your results to the registry.

Review Mode - Submission Disabled
The confirmation toggles and submit button are disabled in review mode.

☐ I confirm that my submission has been reviewed and checked and that warnings from the online checking system have been considered.

☐ I confirm, to the best of my knowledge, that the information and data provided are complete and accurate.

☐ I take full responsibility for the contents of this submission.

SUBMIT RESULTS TO REGISTRY

Submit button is disabled in Review Mode

All sections must be completed before submission.
You can exit the form and return to complete sections you have saved but not completed.

Back

Exit Form

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FORM SECTIONS

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section.
Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and Return to Menu

Save Progress and Return to Menu

Print Section

Provide feedback on this section

ISRCTN Results Submission Form

Baseline Characteristics

Generated on: September 30, 2025 at 15:37:48

Print Functionality To Be Added

Print functionality will be added.
This feature will allow you to print or save a PDF of your completed section

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ISRCTN Results Submission Form - Baseline Characteristics

Close Print Dialogue

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Potential Conflicts of Interest:

WHO requirement: Conflicts of interest for study steering group members are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Not easy

2. What suggestions would you make to improve this section?

- Suggest defining conflicts of interest. (There is no definition on the web form or any links to where this information can be found.) Also define who is considered a steering committee member.

POTENTIAL CONFLICTS OF INTEREST

The World Health Organisation (WHO) requires that conflicts of interest for study steering group members are included in registry summary results

Was there a study steering committee for your study?

☐ Yes

☐ No

[Check Your Submission](#)

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

[Mark Complete and Return to Menu](#) [Save Progress and Return to Menu](#) [Print Section](#)

[Close feedback form](#)

POTENTIAL CONFLICTS OF INTEREST

The World Health Organisation (WHO) requires that conflicts of interest for study steering group members are included in registry summary results

Was there a study steering committee for your study?

☒ Yes

☐ No

Please select one of the options below: [Help](#)

☐ Potential conflicts of interest for study steering group members are summarised with the peer reviewed journal article for this study

☐ I will summarise potential conflicts of interest for study steering group members using the registry form

POTENTIAL CONFLICTS OF INTEREST

The World Health Organisation (WHO) requires that conflicts of interest for study steering group members are included in registry summary results

Was there a study steering committee for your study?

☐ Yes

☒ No

[Check Your Submission](#)

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

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Protocol & Statistical Analysis Plan:

WHO requirement: The final study protocol (with version number, date and history of amendments) is included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Moderately easy

2. What suggestions would you make to improve this section?

No comments

PROTOCOL

The World Health Organisation (WHO) requires that the final study protocol (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Please select one of the options below:

☐ I provided my final study protocol to ISRCTN when I registered the study

☐ I will upload my final study protocol in .pdf format

☐ I will provide a Digital Object Identifier (DOI) for my final study protocol

STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

☐ Yes

☐ No

[Check Your Submission](#)

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

[Mark Complete and Return to Menu](#) [Save Progress and Return to Menu](#) [Print Section](#)

[Provide feedback on this section](#)

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PROTOCOL

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Information should be redacted to comply with applicable privacy laws

Please select one of the options below:

- ☒ I provided my final study protocol to ISRCTN when I registered the study
- ☐ I will upload my final study protocol in .pdf format
- ☐ I will provide a Digital Object Identifier (DOI) for my final study protocol

STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- ☐ Yes
- ☐ No

PROTOCOL

The World Health Organisation (WHO) requires that the final study protocol (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Please select one of the options below:

- ☐ I provided my final study protocol to ISRCTN when I registered the study
- ☐ I will upload my final study protocol in .pdf format
- ☒ I will provide a Digital Object Identifier (DOI) for my final study protocol

Enter DOI number

Example: 10.1234/abcd.efgh

STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- ☐ Yes
- ☐ No

PROTOCOL

The World Health Organisation (WHO) requires that the final study protocol (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Please select one of the options below:

- ☐ I provided my final study protocol to ISRCTN when I registered the study
- ☒ I will upload my final study protocol in .pdf format
- ☐ I will provide a Digital Object Identifier (DOI) for my final study protocol

Please select the protocol PDF file to upload:

Upload Protocol: (0)

Accepted format: PDF (.pdf)

STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- ☐ Yes
- ☐ No

STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- ☐ Yes
- ☒ No

Check Your Submission

STATISTICAL ANALYSIS PLAN

The World Health Organisation (WHO) requires that the final statistical analysis plan document (with version number, date and history of amendments) is included in registry summary results

Information should be redacted to comply with applicable privacy laws

Is there a statistical analysis plan document for your study?

- ☒ Yes
- ☐ No

Please select one of the options below:

- ☐ I provided my final statistical analysis plan to ISRCTN when I registered the study
- ☐ I will upload my final statistical analysis plan in .pdf format
- ☐ I will provide a Digital Object Identifier (DOI) for my final statistical analysis plan

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Completion Status:

WHO requirement: The completion status and completion date for your study are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Moderately easy

2. What suggestions would you make to improve this section?

No comments

COMPLETION STATUS

The World Health Organisation (WHO) requires that the completion status and completion date for your study is included in registry summary results

Please select the option from the dropdown box that best describes the completion status for your study:

Stopped early

Please enter the date your study reached its completion status:

30/09/2025

Close

Unless otherwise stated in the protocol:

- For interventional studies: This is the date the last participant completed their final visit for assessment of the primary outcome measure, secondary outcome measures and adverse events (the last participant's last visit)
- For non-interventional studies: This is the date of the last patient observation
- For database or registry studies: This is the date the analysis was completed or discontinued

Please provide reasons why your study was stopped early:

e.g., met a predefined stopping rule for efficacy, met a predefined stopping rule for futility, met a predefined stopping rule for safety, stopped for safety concerns, funding issues

Check Your Submission

COMPLETION STATUS

The World Health Organisation (WHO) requires that the completion status and completion date for your study is included in registry summary results

Please select the option from the dropdown box that best describes the completion status for your study:

Completed as expected

Please enter the date your study reached its completion status:

30/09/2025

Close

Unless otherwise stated in the protocol:

- For interventional studies: This is the date the last participant completed their final visit for assessment of the primary outcome measure, secondary outcome measures and adverse events (the last participant's last visit)
- For non-interventional studies: This is the date of the last patient observation
- For database or registry studies: This is the date the analysis was completed or discontinued

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Publication Status:

WHO requirement: The date and digital object identifier for the journal publication of the primary results are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Moderately easy

2. What suggestions would you make to improve this section?

No comments

PUBLICATION STATUS

The World Health Organisation (WHO) requires that the date and digital object identifier for the journal publication of the primary results is included in registry summary results

Have the primary results for your study been published in a peer-reviewed journal article? [Help](#)

☐ Yes

☐ No

[Check Your Submission](#)

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

[Mark Complete and Return to Menu](#)

[Save Progress and Return to Menu](#)

[Print Section](#)

[Provide feedback on this section](#)

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PUBLICATION STATUS

The World Health Organisation (WHO) requires that the date and digital object identifier for the journal publication of the primary results is included in registry summary results

Have the primary results for your study been published in a peer-reviewed journal article? [Close](#)

Primary Results Definition:

Primary results refer to findings related to the primary outcome(s) of your study as pre-specified in your protocol. They typically include:

- Main findings related to the primary objective(s) of the study
- Results that address the primary hypothesis or research question
- Data analysis of the pre-specified primary endpoint(s)

Note: Congress abstracts or preliminary communications are not considered complete publications of primary results. This question asks whether a peer-reviewed journal article reporting the primary outcome results has been published.

☒ Yes

☐ No

Please enter the date the peer-reviewed journal article was published:

dd/mm/yyyy

Is there a Digital Object Identifier (DOI) for this publication?

☐ Yes

☐ No

[Check Your Submission](#)

PUBLICATION STATUS

The World Health Organisation (WHO) requires that the date and digital object identifier for the journal publication of the primary results is included in registry summary results

Have the primary results for your study been published in a peer-reviewed journal article? [Close](#)

Primary Results Definition:

Primary results refer to findings related to the primary outcome(s) of your study as pre-specified in your protocol. They typically include:

- Main findings related to the primary objective(s) of the study
- Results that address the primary hypothesis or research question
- Data analysis of the pre-specified primary endpoint(s)

Note: Congress abstracts or preliminary communications are not considered complete publications of primary results. This question asks whether a peer-reviewed journal article reporting the primary outcome results has been published.

☐ Yes

☒ No

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Plain Language Summary of Results:

The WHO does not require plain language summaries (PLSs) of results to be included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Moderately easy

2. What suggestions would you make to improve this section?

No comments

PLAIN LANGUAGE SUMMARY OF RESULTS

The World Health Organisation (WHO) does not require plain language summaries (PLSs) of results to be included in registry summary results

You are however encouraged to provide a PLS of your results to help participants and others understand the results of your study

Please review guidance for plain language summaries available [here](#)

See Help for information on posting a PLS of results to meet UK regulations

Close

Plain Language Summary Requirement:

UK Regulations for clinical trials of medicines for human use require that:

- Unless there is a deferral or waiver, within 12 months after the conclusion of a clinical trial sponsors must offer a summary of results written in a manner understandable to laypersons to all relevant persons
- Relevant persons include trial participants, their legal representatives or caregivers, and next of kin (in case of deceased participants)

Posting a plain language summary of results to this registry and providing a link to participants and others is one way you can meet this requirement

Please select one of the options below:

☐ I will upload a plain language summary of results in .pdf format

☐ I will provide a Digital Object Identifier (DOI) for a plain language summary of results

☐ I will make a plain language summary of results available through a different mechanism

☐ I will not make a plain language summary of results available

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and Return to MenuSave Progress and Return to MenuPrint Section

[Provide feedback on this section](#)



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Data Sharing Plan:

WHO requirement: The data sharing plans are updated as needed after study completion.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Moderately easy

2. What suggestions would you make to improve this section?

- General comment: It would be helpful to mark on the form the fields from IRAS which are posted in the public domain.
- In some organisations, another department populates the IRAS form, so perhaps it would be helpful to have an option for the person completing the form to include additional member contact details; to allow the form submission to be viewed by the other interested groups; and to show which fields were selected to opt in for auto-registration so the interested groups can also prepare for the next steps and maintain compliance.
- Formatting: In instances where there is a prompt to select one option ("Please select one of the options below:"), square checkboxes are used. Typically, square boxes are used when there are multiple options to select. Therefore, we suggest changing square boxes to circular because circles are usually used when there is only one option to select.

Note: This comment applies to all instances throughout the form when square boxes are used and the user is required to select only one option.

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DATA SHARING

The World Health Organisation (WHO) requires that data sharing plans are updated as needed after study completion

This is the data sharing plan you provided when you registered this study:

[Data sharing plan from ISRCTN or ClinicalTrials.gov displayed here].

Please select one of the options below:

- ☐ The data sharing plan for my study has not changed
- ☐ I will update the data sharing plan for my study
(also select this option if your study is not registered on ISRCTN or ClinicalTrials.gov)

[Check Your Submission](#)

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

[Mark Complete and
Return to Menu](#)

[Save Progress and
Return to Menu](#)

[Print Section](#)

[Provide feedback on this section](#)



DATA SHARING

The World Health Organisation (WHO) requires that data sharing plans are updated as needed after study completion

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[Data sharing plan from ISRCTN or ClinicalTrials.gov displayed here].

Please select one of the options below:

- ☒ The data sharing plan for my study has not changed
- ☐ I will update the data sharing plan for my study
(also select this option if your study is not registered on ISRCTN or ClinicalTrials.gov)

Check Your Submission



DATA SHARING

The World Health Organisation (WHO) requires that data sharing plans are updated as needed after study completion

This is the data sharing plan you provided when you registered this study:

[Data sharing plan from ISRCTN or ClinicalTrials.gov displayed here].

Please select one of the options below:

- ☐ The data sharing plan for my study has not changed
- ☒ I will update the data sharing plan for my study
(also select this option if your study is not registered on ISRCTN or ClinicalTrials.gov)

Update or provide your data sharing plan:

[Data sharing plan from ISRCTN or ClinicalTrials.gov displayed here].

[Check Your Submission](#)



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Participant Flow:

WHO requirement: Information relating to the flow of participants through the study, from enrolment to inclusion in the main analysis of the primary outcome measure, is included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Not easy

2. What suggestions would you make to improve this section?

- General comment regarding the 'Mark All Complete' button in the top left corner of the main menu: Suggestion for the system to include additional verification and pointers for the required amendments (within each section and on the contents/main menu page) because this button may be selected without the record being completed correctly.
- This section is complex and must be completed before being able to continue to the remaining sections. The system includes validation checks but could be improved for user-friendliness.



PARTICIPANT FLOW

The World Health Organisation (WHO) requires that information relating to the flow of participants through the study from enrollment to inclusion in the main analysis of the primary outcome measure is included in registry summary results

You have the option to also provide participant flow information for other parts, cohorts or periods of your study where this would help others understand your study

Information on participant flow is based on the CONSORT approach

[Help](#)

Please select one of the options below:

- ☒ I will provide participant flow information for WHO requirements only - the number allocated to study arms/groups and included in the main analysis of the primary outcome measure
- ☐ I will provide participant flow information for WHO requirements **and for other parts, cohorts or periods in my study**

Total Number of Participants

Please enter the total number of participants enrolled in your study before allocation to study arms/groups:

Total Participants:

Note: This should be the total number of participants who were enrolled before randomisation or allocation to study arms/groups (e.g., number assessed for eligibility).

PARTICIPANT FLOW

The World Health Organisation (WHO) requires that information relating to the flow of participants through the study from enrollment to inclusion in the main analysis of the primary outcome measure is included in registry summary results

You have the option to also provide participant flow information for other parts, cohorts or periods of your study where this would help others understand your study

Information on participant flow is based on the CONSORT approach

Close

CONSORT 2025 Flow Diagram

The diagram below shows participant progress through the phases of a two group, parallel randomised trial:

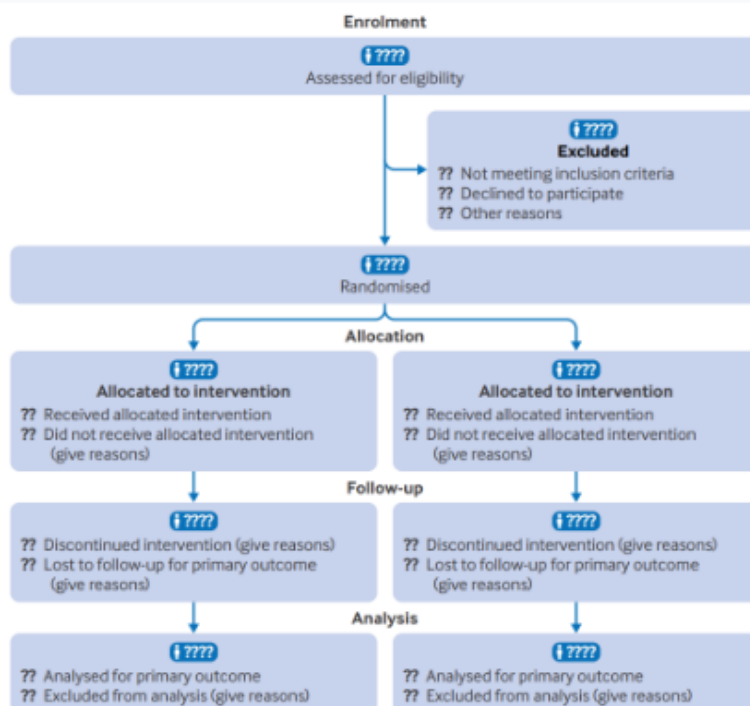


Fig 1 | CONSORT 2025 flow diagram. Flow diagram of participant progress through the phases of a two group, parallel randomised trial (ie, enrolment, intervention allocation, follow-up, and data analysis). CONSORT=Consolidated Standards of Reporting Trials

Close



Study Arms/Groups

Please enter the number of study arms/groups in your study:

[Help](#)

Please enter a description for each arm/group:

Arm/Group 1:

Arm/Group 2:

Note: The number of Arms/Groups and descriptions are applied to all relevant registry tables. If you change the number of Arms/Groups or their descriptions these changes will be applied throughout the form.

Participant Flow Information

Please select how you would like to provide participant flow information:

☒ I will upload participant flow information table(s) and/or figure(s) in .pdf format

i Select this option if it is difficult to use the registry tables to describe participant flow for your study or if it is easier to provide accurate and complete data.

☐ I will provide participant flow information by completing registry tables



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Options:

PDF UPLOAD

Table/Figure Upload

Upload Requirements

Important: Please click "Upload Requirements" above and read the requirements before proceeding with the confirmations below.

☐ I confirm that the tables and/or figures I will upload have been reviewed and checked

☐ I confirm, to the best of my knowledge, that the tables and/or figures I will upload contain complete and accurate data

☐ I confirm that the information I will upload meets WHO requirements and the registry Upload Requirements

Please explain the participant flow (optional):

Provide additional context or explanation about the participant flow in your study...

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and Return to Menu

Save Progress and Return to Menu

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REGISTRY RESULTS TABLE UPLOAD

Participant Flow Information

Please select how you would like to provide participant flow information:

- ☐ I will upload participant flow information table(s) and/or figure(s) in .pdf format

i Select this option if it is difficult to use the registry tables to describe participant flow for your study or if it is easier to provide accurate and complete data.

- ☒ I will provide participant flow information by completing registry tables

Create/Update Table with
Descriptions

Number of Participants

Please complete the table below by entering the number of participants:

Number of Participants	Arm/Group 1	Arm/Group 2	Study Population
Allocated to Study Treatment(s)	0	0	0
Included in the Main Analysis of the Primary Outcome Measure(s)	0	0	0
Included in Study Part, Cohort or Period 1	0	0	0

Reasons for Non-completion for Each Arm/Group

For each arm/group, provide the reasons for exclusion
(Note: There is one table for each arm/group)

Close

Help:

- Enter the number of participants who were excluded for the reasons specified in the table. If a participant was excluded for more than one reason count only one reason (the main reason). Do not count the same participant in more than one row. If no participants were excluded for a specified reason leave the number as "0". Delete rows with all zeros using the button at the bottom of each table.
- For participants who **Did not Receive Any Study Treatment as Allocated** include only participants who were allocated to a study treatment group but did not receive any part of the assigned treatment (e.g., did not start treatment). Do not include participants who received part but not all of the assigned treatment.
- **Lost to Follow-up** specifically refers to participants who were enrolled and assigned to a treatment group but did not complete the study or a study period because they could not be contacted or failed to return for follow-up assessments. This is distinct from other reasons for non-completion, such as adverse events or participant withdrawal.
- If there are other specific reasons that are not included in the table, use the box below the table to add specific reasons to the table. Reasons added in error can be deleted.
- Use the **Other Reason Excluded from Analysis** row for participants excluded from the analysis for reasons not captured elsewhere in the table. For example, if the analysis was conducted in a per-protocol population, include here any participants excluded due to not meeting those criteria (e.g., missing key visits, non-adherence), provided a more specific reason (e.g., protocol violation, withdrawal) does not apply.
- For **interim analyses** add a reason "not recruited at the time of the interim analysis".



Arm/Group 1 - Reasons	Did not Receive Any Study Treatment as Allocated	Excluded from the Main Analysis of the Primary Outcome Measure(s)	Excluded from Study Part, Cohort or Period 1
Adverse Event	0	0	0
Death	0	0	0
Lack of Efficacy	0	0	0
Protocol Violation	0	0	0
Pregnancy	0	0	0
Participant Withdrawal	0	0	0
Withdrawn by Study Investigator	0	0	0
Lost to Follow-up	0	0	0
Other Reason Excluded from Analysis	N/A	0	0

Add another specific reason for Arm/Group 1 (optional):

Add Reason

Delete All Zero Rows (functionality to be added)



Arm/Group 2 - Reasons	Did not Receive Any Study Treatment as Allocated	Excluded from the Main Analysis of the Primary Outcome Measure(s)	Excluded from Study Part, C or Period
Adverse Event	0	0	0
Death	0	0	0
Lack of Efficacy	0	0	0
Protocol Violation	0	0	0
Pregnancy	0	0	0
Participant Withdrawal	0	0	0
Withdrawn by Study Investigator	0	0	0
Lost to Follow-up	0	0	0
Other Reason Excluded from Analysis	N/A	0	0

Add another specific reason for Arm/Group 2 (optional):

Add Reason

Delete All Zero Rows (functionality to be added)

Please explain the participant flow (optional):

Provide additional context or explanation about the participant flow in your study...

Check Your Submission



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Baseline Characteristics:

WHO requirement: Baseline characteristics for age, sex and other relevant characteristics are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Not easy

2. What suggestions would you make to improve this section?

- Users must click on several options to navigate each aspect for completion. An option to reset form fields would be helpful for starting afresh on a particular section or question. Square box options can be unselected, but this is not possible with the circle field options. We suggest simplifying the navigation and data entry user interface experience. The prototype lacks user-friendly features and documentation.
- For sex, the options are: male, female, not recorded as male or female. In some cases – for example, when there is one female in the arm – providing more baseline characteristic information gets you a profile of the patient. There should be an option to show the baseline per overall study so as not to build the profile of a particular patient where the arm is N=1.



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Options:

PDF UPLOAD

BASELINE PARTICIPANT CHARACTERISTICS - POPULATION 1

The World Health Organisation (WHO) requires that baseline characteristics for age, sex and other relevant characteristics are included in registry summary results

This is typically for all participants allocated to study arms/groups

After entering information for this study population, you will have the option to enter baseline characteristics for another study population where this would help others understand your study

For multi-part studies, to provide baseline characteristics for different parts of your study enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g., Dose Ranging Part, Intent-to-Treat Population (all participants allocated to study arms/groups)

Please select the population for baseline characteristics from the dropdown list:

Please select...

Please select one of the options below:

☒ I will upload baseline participant characteristics table(s) for this study population in pdf format

Select this option if it is difficult to use the registry tables to describe baseline characteristics for your study or if it is easier to provide accurate and complete data.

☐ I will provide baseline participant characteristics for this study population by completing registry tables

Table Upload

Upload Requirements

Important: Please click "Upload Requirements" above and read the requirements before proceeding with the confirmations below.

☐ I confirm that the tables I will upload have been reviewed and checked

☐ I confirm, to the best of my knowledge, that the tables I will upload contain complete and accurate data

☐ I confirm that the information I will upload meets WHO requirements and the registry Upload Requirements

Baseline Characteristics for Another Population

Do you want to add baseline characteristics for another study population?
(The WHO does not require that additional populations are included in registry summary results)

☐ Yes

☒ No

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REGISTRY RESULTS TABLES UPLOAD

BASLINE PARTICIPANT CHARACTERISTICS - POPULATION 1

The World Health Organisation (WHO) requires that baseline characteristics for age, sex and other relevant characteristics are included in registry summary results

This is typically for all participants allocated to study arm(s)/group(s)

After entering information for this study population, you will have the option to enter baseline characteristics for another study population where this would help others understand your study

For multi-part studies, to provide baseline characteristics for different parts of your study enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g., Cross-Ranging Part, Inten-to-Treat Population (all participants allocated to study arm(s)/group(s))

Please select the population for baseline characteristics from the dropdown list:

Please select...

Please select one of the options below:

☐ I will upload baseline participant characteristics table(s) for this study population in pdf format

☒ Select this option if it is difficult to use the registry tables to describe baseline characteristics for your study or if it is easier to provide accurate and complete data.

☒ I will provide baseline participant characteristics for this study population by completing registry tables

BASLINE PARTICIPANT CHARACTERISTICS

How many additional baseline characteristics do you want to add beyond Biological Sex and Age?

Note: In this prototype if you add additional characteristics after entering data you will need to select the Create/Update Table button to view those data

0

BIOLOGICAL SEX

Please complete the table below (if required add Gender identities in an Additional Baseline Characteristic table):

Biological Sex Data	Arm/Group 1	Arm/Group 2
Number of Participants with Available Data at Baseline	0	0
Number of Females	0	0
Number of Males	0	0
Number not recorded as Male or Female	0	0

AGE

Please select one of the options below:

☐ I will provide a statistical measure (e.g., mean, median) and a statistical measure of variation (e.g., standard deviation, range) of the age in each study arm/group

☐ I will provide the number of participants in defined age groups in each study arm/group (e.g., 18-45 years; >45 years)

Baseline Characteristics for Another Population

Do you want to add baseline characteristics for another study population?
(The WHO does not require that additional populations are included in registry summary results)

☐ Yes

☒ No

Check Your Submissions

BASLINE PARTICIPANT CHARACTERISTICS - POPULATION 1

Please select the population for baseline characteristics from the dropdown list:

Please select...

Please select one of the options below:

☐ I will upload baseline participant characteristics table(s) for this study population in pdf format

☒ Select this option if it is difficult to use the registry tables to describe baseline characteristics for your study or if it is easier to provide accurate and complete data.

☒ I will provide baseline participant characteristics for this study population by completing registry tables

BASLINE PARTICIPANT CHARACTERISTICS

How many additional baseline characteristics do you want to add beyond Biological Sex and Age?

Note: In this prototype if you add additional characteristics after entering data you will need to select the Create/Update Table button to view those data

0

BIOLOGICAL SEX

Please complete the table below (if required add Gender identities in an Additional Baseline Characteristic table):

Biological Sex Data	Arm/Group 1	Arm/Group 2
Number of Participants with Available Data at Baseline	0	0
Number of Females	0	0
Number of Males	0	0
Number not recorded as Male or Female	0	0

AGE

Please select one of the options below:

☐ I will provide a statistical measure (e.g., mean, median) and a statistical measure of variation (e.g., standard deviation, range) of the age in each study arm/group

☐ I will provide the number of participants in defined age groups in each study arm/group (e.g., 18-45 years; >45 years)

Additional Population 2

Define Population 2

BASLINE PARTICIPANT CHARACTERISTICS - POPULATION 2

The World Health Organisation (WHO) requires that baseline characteristics for age, sex and other relevant characteristics are included in registry summary results

This is typically for all participants allocated to study arm(s)/group(s)

After entering information for this study population, you will have the option to enter baseline characteristics for another study population where this would help others understand your study

For multi-part studies, to provide baseline characteristics for different parts of your study enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g., Cross-Ranging Part, Inten-to-Treat Population (all participants allocated to study arm(s)/group(s))

Please select the population for baseline characteristics from the dropdown list:

Please select...

Please select one of the options below:

☐ I will upload baseline participant characteristics table(s) for this study population in pdf format

☒ Select this option if it is difficult to use the registry tables to describe baseline characteristics for your study or if it is easier to provide accurate and complete data.

☐ I will provide baseline participant characteristics for this study population by completing registry tables

Check Your Submissions



AGE

Please select one of the options below:

- ☒ I will provide a statistical measure (e.g., mean, median) and a statistical measure of variation (e.g., standard deviation, range) of the age in each study arm/group
- ☐ I will provide the number of participants in defined age groups in each study arm/group (e.g., 18-65 years; >65 years)

Age - unit of measurement:

Age - statistical measure:

Age - measure of variation:

Create/Update Table with
Descriptions



AGE

Please select one of the options below:

- ☒ I will provide a statistical measure (e.g., mean, median) and a statistical measure of variation (e.g., standard deviation, range) of the age in each study arm/group
- ☐ I will provide the number of participants in defined age groups in each study arm/group (e.g., 18-65 years; >65 years)

Age - unit of measurement:

Age - statistical measure:

Age - measure of variation:

Create/Update Table with
Descriptions

Other Population

Please complete the table below:

Age Data	Arm/Group 1	Arm/Group 2
Number of Participants with Available Data at Baseline	0	0
Unit of Measurement (units)	units	units
Statistical Measure	0	0
Measure of Variation		



AGE

Please select one of the options below:

- ☐ I will provide a statistical measure (e.g., mean, median) and a statistical measure of variation (e.g., standard deviation, range) of the age in each study arm/group
- ☒ I will provide the number of participants in defined age groups in each study arm/group (e.g., 18-65 years; >65 years)

How many age groups are there for your study?

2

Please enter a description for each age group:

Age Group 1: e.g., <18 years

Age Group 2: e.g., 18-65 years

Create/Update Table with
Descriptions



AGE

Please select one of the options below:

- ☐ I will provide a statistical measure (e.g., mean, median) and a statistical measure of variation (e.g., standard deviation, range) of the age in each study arm/group
- ☒ I will provide the number of participants in defined age groups in each study arm/group (e.g., 18-65 years; > 65 years)

How many age groups are there for your study?

2

Please enter a description for each age group:

Age Group 1: e.g., <18 years

Age Group 2: e.g., 18-65 years

Create/Update Table with
Descriptions

Other Population

Please complete the table below:

Age Data	Arm/Group 1	Arm/Group 2
Number of Participants with Available Data at Baseline	0	0
<18 years - Number of Participants	0	0
18-65 years - Number of Participants	0	0



Additional Population 2

Delete Population 2

BASELINE PARTICIPANT CHARACTERISTICS - POPULATION 2

The World Health Organisation (WHO) requires that baseline characteristics for age, sex and other relevant characteristics are included in registry summary results

This is typically for all participants allocated to study arms/groups

After entering information for this study population, you will have the option to enter baseline characteristics for another study population where this would help others understand your study

For multi-part studies, to provide baseline characteristics for different parts of your study enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g., Dose Ranging Part, Intent-to-Treat Population (all participants allocated to study arms/groups)

Please select the population for baseline characteristics from the dropdown list:

Please select...

Please select one of the options below:

☐ I will upload baseline participant characteristics table(s) for this study population in .pdf format

i Select this option if it is difficult to use the registry tables to describe baseline characteristics for your study or if it is easier to provide accurate and complete data.

☐ I will provide baseline participant characteristics for this study population by completing registry tables

Check Your Submission

Please select the population for baseline characteristics from the dropdown list:

Please select...

Please select...

Intent-to-treat population (all participants as allocated to study arms/groups)

Per-protocol population (only participants who complied with the protocol)

Safety population (all participants who received at least one dose)

Other



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Outcome Measures – Population 1:

WHO requirement: Primary and secondary outcome measure results are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Not easy

2. What suggestions would you make to improve this section?

- In the section for uploading of results, is that needed for individual endpoints or for all of them?
- Clarification is required on how to report the outcome measure for a different population when a different population was selected for the overall Outcome Measures section. This is a system limitation in reporting outcome measures for different populations, whereby only one population can be selected per outcome measure, which may not reflect study complexity.

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OUTCOME MEASURES - POPULATION 1

The World Health Organisation (WHO) requires that primary and secondary outcome measure results are included in registry summary results

You have the option to include other outcome measures where this would help others understand your study

Where the same or different outcome measures are analysed in different populations, enter results for each population in turn

For multi-part studies, enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g. Dose Ranging Part. Intent to Treat Population (all participants allocated to study arms/groups)

[See Your Registered Outcome Measures](#)

Please select the analysis population from the dropdown list:

Please select...

How many outcome measures are you reporting for this study population?

1

Are you reporting all the outcome measures you registered for this study population?

Note: The inclusion of all registered outcome measures will be checked as part of the editorial review of your submission. If results for an outcome measure are not being reported for this study population please provide an explanation here

☒ Yes

☐ No

POPULATION 1: OUTCOME MEASURE 1

Please select the outcome measure type from the dropdown list:

Primary

Please enter a description for the outcome measure
(this can be copied from your registered outcome measures if shown above):

e.g., systolic blood pressure at 12 weeks, change from baseline in body weight, percentage change in LDL cholesterol, difference in response rates between treatment groups

OUTCOME MEASURES - POPULATION 1

The World Health Organisation (WHO) requires that primary and secondary outcome measure results are included in registry summary results

You have the option to include other outcome measures where this would help others understand your study

Where the same or different outcome measures are analysed in different populations, enter results for each population in turn

For multi-part studies, enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g. Dose Ranging Part. Intent to Treat Population (all participants allocated to study arms/groups)

[Close](#)

These are the outcome measures registered for this study:

Primary outcome measure

Primary outcome measure(s) from ISRCTN or ClinicalTrials.gov displayed here

Secondary outcome measures

Secondary outcome measures from ISRCTN or ClinicalTrials.gov displayed here

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See Your Registered Outcome Measures

Please select the analysis population from the dropdown list:

Other

Please enter a description for the analysis population:

For example: Modified intent-to-treat population

How many outcome measures are you reporting for this study population?

1

Are you reporting all the outcome measures you registered for this study population?

Note : The inclusion of all registered outcome measures will be checked as part of the editorial review of your submission. If results for an outcome measure are not being reported for this study population please provide an explanation here

☒ Yes

☐ No



Are you reporting all the outcome measures you registered for this study population?

Note : The inclusion of all registered outcome measures will be checked as part of the editorial review of your submission. If results for an outcome measure are not being reported for this study population please provide an explanation here

☒ Yes
☐ No

POPULATION 1: OUTCOME MEASURE 1

Please select the outcome measure type from the dropdown list:

Primary

Please enter a description for the outcome measure
(this can be copied from your registered outcome measures if shown above):

e.g., systolic blood pressure at 12 weeks, change from baseline in body weight, percentage change in LDL cholesterol, difference in response rates between treatment groups

Is this Outcome Measure included in your protocol registration?

☐ Yes
☒ No

Please provide an explanation:

For example: There was a protocol amendment but the registration was not updated (see study protocol)

Outcome Measure Format

Please select one of the options below:
[To be added: The tables or figures already uploaded provide the results for this outcome measure]

☐ I will upload table(s) and/or figure(s) in .pdf format showing the results for this outcome measure

i Select this option if it is difficult to use the registry tables to describe the results for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry results tables for this outcome measure

[Check Your Submission](#)



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How many outcome measures are you reporting for this study population?

Are you reporting all the outcome measures you registered for this study population?

Note: The inclusion of all registered outcome measures will be checked as part of the editorial review of your submission. If results for an outcome measure are not being reported for this study population please provide an explanation here

- ☐ Yes
☒ No

Please provide the number of registered outcome measures you are not reporting

Please provide the description of each non-reported outcome measure and reasons for not reporting:

Outcome Measure 1 not reported:

e.g., Secondary endpoint: Five year progression free survival - Data for this outcome measure is being collected/has not been collected

POPULATION 1: OUTCOME MEASURE 1

Please select the outcome measure type from the dropdown list:

Primary

Please enter a description for the outcome measure
(this can be copied from your registered outcome measures if shown above):

e.g., systolic blood pressure at 12 week, change from baseline in body weight, percentage change in ldl cholesterol, difference in response rates between treatment groups

Is this Outcome Measure included in your protocol registration?

- ☐ Yes
☒ No

Please provide an explanation:

For example: there was a protocol amendment but the registration was not updated (see study protocol)

Outcome Measure Format

Please select one of the options below:

(to be added: The tables or figures already uploaded provide the results for this outcome measure)

- ☐ I will upload table(x) and/or figure(x) in .pdf format showing the results for this outcome measure

Select this option if it is difficult to use the registry tables to describe the results for your study or if it is easier to provide accurate and complete data.

- ☐ I will complete the registry results tables for this outcome measure

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Options:

PDF UPLOAD

Outcome Measure Format

Please select one of the options below:
[To be added: The tables or figures already uploaded provide the results for this outcome measure]

☒ I will upload table(s) and/or figure(s) in .pdf format showing the results for this outcome measure

i Select this option if it is difficult to use the registry tables to describe the results for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry results tables for this outcome measure

Table/Figure Upload

[Upload Requirements](#)

Important: Please click "Upload Requirements" above and read the requirements before proceeding with the confirmations below.

☐ I confirm that the tables and/or figures I will upload have been reviewed and checked

☐ I confirm, to the best of my knowledge, that the tables and/or figures I will upload contain complete and accurate data

☐ I confirm that the information I will upload meets WHO requirements and the registry Upload Requirements

[Check Your Submission](#)

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

[Mark Complete and Return to Menu](#)

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REGISTRY RESULTS TABLES UPLOAD

Outcome Measure Format

Please select one of the options below:
[To be added: The tables or figures already uploaded provide the results for this outcome measure]

☐ I will upload table(s) and/or figure(s) in .pdf format showing the results for this outcome measure

1 Select this option if it is difficult to use the registry tables to describe the results for your study or if it is easier to provide accurate and complete data.

☒ I will complete the registry results tables for this outcome measure

Study Arm/Group Changes for Efficacy

Is the number and names of study arms/groups for the results of this outcome measure the same as those entered in the Participant Flow section?

[Help](#)

☒ Yes

☐ No

Results Table Types

Please select the type(s) of table to report results for this outcome measure (you may select more than one table type):

☐ Table to report outcome measures at one or more timepoints

☐ Table to report changes between one or more defined timepoints (e.g., Baseline and End of Treatment)

☐ Table to report derived outcome measures from study measurements (e.g., $T_{1/2}$, Cmax, AUC)

[Check Your Submission](#)

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

[Mark Complete and Return to Menu](#) [Save Progress and Return to Menu](#) [Print Section](#)

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Is this Outcome Measure included in your protocol registration?

☐ Yes

☒ No

Please provide an explanation:

For example: There was a protocol amendment but the registration was not updated (see study protocol)

Outcome Measure Format

Please select one of the options below:

[To be added: The tables or figures already uploaded provide the results for this outcome measure]

☐ I will upload table(s) and/or figure(s) in .pdf format showing the results for this outcome measure

i Select this option if it is difficult to use the registry tables to describe the results for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry results tables for this outcome measure

[Check Your Submission](#)



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Adverse Events – Population 1:

WHO requirement: Adverse events (AEs) for all-cause mortality (death), serious adverse events and other adverse events are included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Not easy

2. What suggestions would you make to improve this section?

- Adverse Events for Another Population:

“Do you want to add adverse events for another study population?

(The WHO does not require that additional populations are included in registry summary results.)”

Clarification required here – is this talking about any sub study or something else?

- The terms “another study population” and “additional populations” should be defined in the form to avoid ambiguity.

ADVERSE EVENTS - POPULATION 1

The World Health Organisation (WHO) requires that adverse events (AEs) for all cause mortality (death), serious adverse events and other adverse events are included in registry summary results

Close

Definitions

Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a treatment (e.g., a pharmaceutical product) and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a treatment, whether or not related to the treatment.

Serious Adverse Event (SAE)

Any untoward medical occurrence that at any dose:

- results in death,
- is life-threatening,
- requires inpatient hospitalisation or prolongation of existing hospitalisation,
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect.

Medical and scientific judgment should be exercised in deciding whether other situations should be considered serious adverse events, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed.

Adverse Event Data Collection

Please provide a description for how adverse event data were collected and assessed (optional):

e.g., systematic such as recorded on a case report form or non-systematic such as passive self reporting

Please provide the adverse event dictionary or vocabulary used (optional):

e.g., SNOMED CT, MedDRA (12.0)

After entering information for this study population, you will have the option to enter adverse events for another study population where this would help others understand your study

For multi-part studies, to provide adverse events for different parts of your study enter each part in turn as a different population. Select Other from the dropdown box below and provide a part description and the population e.g., Dose Ranging Part, Intent to Treat Population (all participants allocated to study arms/groups)



Population for Adverse Events

Please select the population used for adverse event reporting:

Please select... ▾

Time Periods for Adverse Event Reporting

How many time periods for AE reporting do you want to include for this population?
(Note: In this prototype changing the number of time periods after entering table data will reset the tables)

Number of time periods:

Time Period 1

Please describe the time period for AE reporting:

e.g., on treatment plus 6 months follow-up

Study Arm/Group Changes for Safety

Is the number and names of study arms/groups the same as you entered in the Participant Flow section? Close

The study arm/group names may be different compared with those you entered in the Participant Flow section.

For example, a cross-over trial may have two study groups:

- Group 1: Active Treatment followed by Placebo
- Group 2: Placebo followed by Active Treatment

For the assessment of adverse events, participants who received the Active Treatment may be compared with participants who received Placebo.

☒ Yes

☐ No



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POPULATION 1 - TIME PERIOD 1

No description provided

ALL-CAUSE MORTALITY - POPULATION 1

ALL-Cause Mortality

Were there any deaths in your study?

☐ Yes

☐ No

SERIOUS ADVERSE EVENTS (SAEs) - POPULATION 1

Serious Adverse Events Reporting Method

Please select one of the options below

☐ I will upload tables in pdf format with serious adverse event data

☒ Select this option if it is difficult to use the registry tables to describe serious adverse events for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry table for serious adverse events

OTHER ADVERSE EVENTS - POPULATION 1

Other Adverse Event Reporting

Select the frequency threshold for reporting Other Adverse Events (optional):

☐ 0% (no threshold, all adverse events reported)

☐ 1% (adverse events in greater than 1% of participants in any arm/group are reported)

☐ 5% (adverse events in greater than 5% of participants in any arm/group are reported)

Other Adverse Events Reporting Method

Please select one of the options below

☐ I will upload tables in pdf format with Other Adverse Event data

☒ Select this option if it is difficult to use the registry tables to describe other adverse event data for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry table for Other Adverse Event data

Adverse Events for Another Population

Do you want to add adverse events for another study population?
(The WHO does not require that additional populations are included in registry summary results)

☐ Yes

☒ No

Check Your Submission

POPULATION 1 - TIME PERIOD 1

No description provided

ALL-CAUSE MORTALITY - POPULATION 1

ALL-Cause Mortality

Were there any deaths in your study?

☐ Yes

☒ No

SERIOUS ADVERSE EVENTS (SAEs) - POPULATION 1

Serious Adverse Events Reporting Method

Please select one of the options below

☐ I will upload tables in pdf format with serious adverse event data

☒ Select this option if it is difficult to use the registry tables to describe serious adverse events for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry table for serious adverse events

OTHER ADVERSE EVENTS - POPULATION 1

Other Adverse Event Reporting

Select the frequency threshold for reporting Other Adverse Events (optional):

☐ 0% (no threshold, all adverse events reported)

☐ 1% (adverse events in greater than 1% of participants in any arm/group are reported)

☐ 5% (adverse events in greater than 5% of participants in any arm/group are reported)

Other Adverse Events Reporting Method

Please select one of the options below

☐ I will upload tables in pdf format with Other Adverse Event data

☒ Select this option if it is difficult to use the registry tables to describe other adverse event data for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry table for Other Adverse Event data

Adverse Events for Another Population

Do you want to add adverse events for another study population?
(The WHO does not require that additional populations are included in registry summary results)

☐ Yes

☒ No

Check Your Submission

POPULATION 1 - TIME PERIOD 1

No description provided

ALL-CAUSE MORTALITY - POPULATION 1

ALL-Cause Mortality

Were there any deaths in your study?

☒ Yes

☐ No

ALL-Cause Mortality Reporting Method

Please select one of the options below

☐ I will upload tables in pdf format with all-cause mortality data

☒ Select this option if it is difficult to use the registry tables to describe all-cause mortality for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry table for all-cause mortality

SERIOUS ADVERSE EVENTS (SAEs) - POPULATION 1

Serious Adverse Events Reporting Method

Please select one of the options below

☐ I will upload tables in pdf format with serious adverse event data

☒ Select this option if it is difficult to use the registry tables to describe serious adverse events for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry table for serious adverse events

OTHER ADVERSE EVENTS - POPULATION 1

Other Adverse Event Reporting

Select the frequency threshold for reporting Other Adverse Events (optional):

☐ 0% (no threshold, all adverse events reported)

☐ 1% (adverse events in greater than 1% of participants in any arm/group are reported)

☐ 5% (adverse events in greater than 5% of participants in any arm/group are reported)

Other Adverse Events Reporting Method

Please select one of the options below

☐ I will upload tables in pdf format with Other Adverse Event data

☒ Select this option if it is difficult to use the registry tables to describe other adverse event data for your study or if it is easier to provide accurate and complete data.

☐ I will complete the registry table for Other Adverse Event data

Adverse Events for Another Population

Do you want to add adverse events for another study population?
(The WHO does not require that additional populations are included in registry summary results)

☐ Yes

☒ No

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Study Conclusion:

(Optional Field) The WHO does not require study limitations or a study conclusion to be included in the registry summary results.

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Moderately easy

2. What suggestions would you make to improve this section?

No comments

STUDY CONCLUSION (Optional)

The World Health Organisation (WHO) does not require study limitations or a study conclusion to be included in registry summary results

Complete this section if it would help others understand your study but carefully consider the information below.

Important: Prior Publication Considerations

Please note that the ICMJE will not consider as prior publication the posting of trial results in any registry if results are limited to a brief structured abstract or tables (to include study participants enrolled, baseline characteristics, primary and secondary outcomes and adverse events)

However, journals may consider posting extensive descriptions of study limitations and conclusions to be prior publication. If you are in doubt, to ensure your submission does not impact journal publication, please check with your target journal before completing this section.

Important: Content must be factual and non-promotional

Both study limitations and conclusions should be scientific, balanced and factual representations of the study. The content must not include promotional language. The registrant takes sole responsibility for all statements made.

Study Limitations

If appropriate, please describe limitations of the trial.

Examples: Early termination leading to small numbers of subjects analysed. Technical problems with measurement leading to unreliable or uninterpretable data. We recommend you provide numbered points or bullet points

Study Conclusion

Please provide a summary of the results (efficacy and adverse events) and the study conclusion with reference to the study hypothesis

Enter study conclusion. We recommend you provide numbered points or bullet points.

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and Return to Menu

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Share Reusable Data:

Have you uploaded (or do you intend to upload) one or more PDF files of your results in any of the following sections: Participant Flow, Baseline Characteristics, Outcome Measures, Statistical Results or Adverse Events?

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

Very easy | Moderately easy | Not easy

PHUSE Response Selection:

Not easy

2. What suggestions would you make to improve this section?

- PDF vs. CSV file uploading should be noted in individual sections where applicable. Currently, CSV uploads are only mentioned towards the end of the form within the 'Share Reusable Data' section. We recommend being more specific earlier on so users know before they reach the final section.

SHARE REUSABLE DATA

Have you uploaded (or do you intend to upload) one or more PDF files of your results in any of the following sections, Participant Flow, Baseline Characteristics, Outcome Measures, Statistical Results or Adverse Events?

☐ Yes

☐ No

Check Your Submission

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SHARE REUSABLE DATA

Have you uploaded (or do you intend to upload) one or more PDF files of your results in any of the following sections, Participant Flow, Baseline Characteristics, Outcome Measures, Statistical Results or Adverse Events?

☒ Yes

☐ No

PDF files meet needs for transparency but it can be difficult for others to extract and re-use data in PDF files.

We therefore ask you to upload a CSV file containing the summary results you have submitted in PDF files. Do not upload individual participant data.

Please select one of the options below:

☐ I will provide a CSV file of my results

☐ I am not able to provide a CSV file of my results

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and
Return to Menu

Save Progress and
Return to Menu

Print Section

[Provide feedback on this section](#)



SHARE REUSABLE DATA

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☒ Yes

☐ No

PDF files meet needs for transparency but it can be difficult for others to extract and re-use data in PDF files.

We therefore ask you to upload a CSV file containing the summary results you have submitted in PDF files. Do not upload individual participant data.

Please select one of the options below:

☒ I will provide a CSV file of my results

☐ I am not able to provide a CSV file of my results

Upload
Requirements

Important: Please click "Upload Requirements" above and read the requirements before proceeding with the confirmations below.

☐ I confirm that the CSV file I will upload has been reviewed and checked

☐ I confirm, to the best of my knowledge, that the CSV file I will upload contains complete and accurate data

☐ I confirm that the information I will upload meets the registry Upload Requirements

Check Your Submission

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

Mark Complete and
Return to Menu

Save Progress and
Return to Menu

Print Section

[Provide feedback on this section](#)



SHARE REUSABLE DATA

Have you uploaded (or do you intend to upload) one or more PDF files of your results in any of the following sections, Participant Flow, Baseline Characteristics, Outcome Measures, Statistical Results or Adverse Events?

☒ Yes

☐ No

PDF files meet needs for transparency but it can be difficult for others to extract and re-use data in PDF files.

We therefore ask you to upload a CSV file containing the summary results you have submitted in PDF files. Do not upload individual participant data.

Please select one of the options below:

☐ I will provide a CSV file of my results

☒ I am not able to provide a CSV file of my results

[Check Your Submission](#)

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

[Mark Complete and
Return to Menu](#)

[Save Progress and
Return to Menu](#)

[Print Section](#)

[Provide feedback on this section](#)



SHARE REUSABLE DATA

Have you uploaded (or do you intend to upload) one or more PDF files of your results in any of the following sections, Participant Flow, Baseline Characteristics, Outcome Measures, Statistical Results or Adverse Events?

☐ Yes

☒ No

As you have completed registry tables the data you have provided can be easily extracted and re-used.

[Check Your Submission](#)

Important: You are required to Check Your Submission before you can complete this section. Errors need to be corrected before you can complete this section. Please note that some Warnings are generated with AI technology that may make mistakes.

[Mark Complete and
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Submission confirmation denoted by 'Feedback Submitted' for each section:

POTENTIAL CONFLICTS OF INTEREST

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☐ Moderately easy

☒ Not easy

2. What suggestions would you make to improve this section?

- Suggestion to define Conflicts of Interest (currently there is no definition on the web form or any links to where this information can be found). Also define who is considered as a steering committee member.

Feedback Submitted



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PROTOCOL & STATISTICAL ANALYSIS PLAN

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☒ Moderately easy

☐ Not easy

2. What suggestions would you make to improve this section?

No comments

Feedback Submitted

✓ Thank you! Your feedback has been submitted successfully.

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COMPLETION STATUS

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Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☒ Moderately easy

☐ Not easy

2. What suggestions would you make to improve this section?

No comments

Feedback Submitted

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PUBLICATION STATUS

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☒ Moderately easy

☐ Not easy

2. What suggestions would you make to improve this section?

No comments

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PLAIN LANGUAGE SUMMARY OF RESULTS

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☒ Moderately easy

☐ Not easy

2. What suggestions would you make to improve this section?

No comments

Feedback Submitted

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DATA SHARING

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☒ Moderately easy

☐ Not easy

2. What suggestions would you make to improve this section?

- General comment: Clarity regarding which fields from IRAS are posted in the public domain would be helpful to mark up these clearly on the form.
- In some organisations, another department populates the IRAS form so perhaps it would be helpful to include an option for the person completing the form to include

Submit Feedback



2. What suggestions would you make to improve this section?

additional member contact details allowing the form submission to also easily be viewed by the other interested groups regarding this activity, and which fields were selected to opt in for auto-registration so they can also prepare ahead for the next steps and maintain compliance.

Feedback
Submitted

✓ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

- Formatting: In instances where there is a prompt to select one option ("Please select one of the options below:"), square checkboxes are used. Typically, square boxes are used where multiple options can be selected. Therefore, suggestion to change square boxes to circular instead as circles are usually used when requiring only one option to be selected.

Feedback
Submitted

✓ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

option to be selected.

Note: This comment applies to all instances throughout the form where square boxes are used when only one option is required to be selected by the user.

Feedback
Submitted

✓ Thank you! Your feedback has been submitted successfully.



PARTICIPANT FLOW

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☐ Moderately easy

☒ Not easy

2. What suggestions would you make to improve this section?

- General comment regarding the "Mark All Complete" button in the top left corner of the main menu: Suggestion for the system to include additional verification and pointers for the required amendments (within each section and on the contents/main menu page) as this button may be selected without the record being completed correctly.

Feedback Submitted

✔ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

- This section is complex and must be completed before being able to continue to the remaining sections. The system includes validation checks but could be improved for user-friendliness.

Feedback Submitted

✔ Thank you! Your feedback has been submitted successfully.



BASELINE PARTICIPANT CHARACTERISTICS – POPULATION 1

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☐ Moderately easy

☒ Not easy

2. What suggestions would you make to improve this section?

- Users must click on several options to navigate each aspect for completion. An option to reset form fields would also be helpful to start fresh on a particular section or question if needed. Square box options can be unselected, but this is not possible with the circle field options. Suggestion to simplify navigation and data entry user interface experience. Prototype lacks user-friendly features and

Feedback Submitted

✓ Thank you! Your feedback has been submitted successfully.



2. What suggestions would you make to improve this section?

documentation.

- For sex, there are options: male, female, not recorded as male or female. In some cases, for example there could be one female in the arm, when you provide more baseline characteristic information, you can get a profile of this patient. There

Feedback
Submitted

✓ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

- For sex, there are options: male, female, not recorded as male or female. In some cases, for example there could be one female in the arm, when you provide more baseline characteristic information, you can get a profile of this patient. There should be an option either to show the baseline per overall study - in order not to build the profile of a particular patient where the arm is N=1

Feedback
Submitted

✓ Thank you! Your feedback has been submitted successfully.



OUTCOME MEASURES – POPULATION 1

[Close feedback form](#)

Document was last saved: Just now

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

- ☐ Very easy
- ☐ Moderately easy
- ☒ Not easy

2. What suggestions would you make to improve this section?

- In the section for uploading of results, is that needed for each individual endpoint or for all of them?
- Clarification is required on how to report the outcome measure for a different population when a different population was selected for the overall Outcome Measures

Feedback
Submitted

✓ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

population when a different population was selected for the overall Outcome Measures section. This is a system limitation in reporting outcome measures for different populations, whereby only one population can be selected per outcome measure which may not reflect study complexity.

Feedback
Submitted

✓ Thank you! Your feedback has been submitted successfully.



ADVERSE EVENTS – POPULATION 1

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☐ Moderately easy

☒ Not easy

2. What suggestions would you make to improve this section?

- Adverse Events for Another Population:
"Do you want to add adverse events for another study population?
(The WHO does not require that additional populations are included in registry summary results)"

Feedback Submitted

✔ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

Clarification required here, is this talking about any sub study or something else?

- The terms, "another study population" and "additional populations" should be defined in the form as currently there is ambiguity regarding the terms used.

2. What suggestions would you make to improve this section?

- The terms, "another study population" and "additional populations" should be defined in the form as currently there is ambiguity regarding the terms used.

Feedback Submitted

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STUDY CONCLUSION (Optional)

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☒ Moderately easy

☐ Not easy

2. What suggestions would you make to improve this section?

No comments

Feedback Submitted

✔ Thank you! Your feedback has been submitted successfully.

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SHARE REUSABLE DATA

[Close feedback form](#)

Close feedback form

Please help us improve this form by providing feedback on this section:

1. How easy will it be to complete this section?

☐ Very easy

☐ Moderately easy

☒ Not easy

2. What suggestions would you make to improve this section?

- PDF vs. CSV file uploading should be noted in each individual section where this is applicable. Also, suggestion to state clearly earlier on in the form specifying which sections a CSV would be acceptable. Currently, CSV uploads are only mentioned towards the end of the form within this 'Share Reusable Data' section. Recommendation to be more specific earlier on so users know before they reach the final section of the

Feedback Submitted

✔ Thank you! Your feedback has been submitted successfully.

2. What suggestions would you make to improve this section?

applicable. Also, suggestion to state clearly earlier on in the form specifying which sections a CSV would be acceptable. Currently, CSV uploads are only mentioned towards the end of the form within this 'Share Reusable Data' section. Recommendation to be more specific earlier on so users know before they reach the final section of the form.

Feedback Submitted

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